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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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CHARLES A MUSERLIAN
BIERMAN MUSERLIAN & LUCAS
600 THIRD AVENUE
NEW YORK, NY 10016

EXAMINER

RIMELL, SAMUEL G

ART UNIT

PAPER NUMBER

2175

DATE MAILED: 04/17/2003

16

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/308,195

Applicant(s)

THIBAUT ET AL.

Examiner

Sam Rimell

Art Unit

2175

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-6 and 10-16 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 2-6, 10-16 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

SAM RIMELL
PRIMARY EXAMINER

Art Unit: 2166

Claims 15 and 16 are objected to for minor informalities involving spelling. In claim 15, last paragraph, the phrases "carrie8ed" and "imputing" should be "carried" and "inputting". In claim 16, last paragraph, the phrase "imputing" should be "inputting".

Claims 2-8 and 10-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 15: The phrase "several entities, optionally remote" is indefinite. In particular, it is not clear which of the entities are supposed to be considered remote (none, one, more than one, or all). In addition, for entities that are designated as being remote, it is not clear what the entities are remote from. Are the entities remote from each other or remote from some central station?

Claim 16: The remarks of claim 15 apply to claim 16.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2-8 and 10-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over MDS Health Group Limited, hereafter referred to as "MDS".

Claim 15: MDS discloses a computer network involving several entities, such as an operational entity (22, 26, 37, 30) and a preparation laboratory (workstations 10). MDS further discloses functional steps of sequential and conditional validation, as shown in the flow chart of FIG. 2 and FIG. 5. Any step in the flow chart in which a decision must be made (as indicated by a diamond shaped block in the flow chart) reads as a step of conditional validation. All the steps

Art Unit: 2166

in the flow chart are sequential steps. Based on the data collected, a certification is issued at the last step (FIG. 10 illustrating release of results). Any anomalies detected are reported in the result release of FIG. 10.

MDS only differs from claim 1 in that it does not disclose re-injecting cells. However, Examiner takes Official Notice that it is well known in the art to perform dialysis treatment where blood cells are removed from the body and subsequently re-injected. It would have been obvious to one of ordinary skill in the art to modify MDS to be used in the well known environment of a dialysis treatment, where some of the blood cells removed from the body are sampled and tested, and the remaining untested cells are returned to the body. This is a conventional protocol used in dialysis treatment to test the effectiveness of the treatment.

MDS further discloses the inputting post-reinjection follow up information, which is the entry of data from subsequent tests (page 6, line 17).

Claim 16: See remarks for claim 15.

Claim 2: FIG. 3 illustrates the requirement for a password input.

Claim 3: FIG. 3 is the certification screen page.

Claim 4: FIG. 7i shows a coded identification field in the top left corner (field for barcode number).

Claim 5: The step of printing certain screen pages, particularly the results screen page (FIG. 10) is well within the scope of the MDS reference.

Claim 6: Each test culture constitutes a "kit". The transfer of the kits to the testing laboratory is monitored by attributing a bar code to each kit so that each kit can be recorded as

Art Unit: 2166

existing in the laboratory (See top left corner of FIG. 7(a) where bar codes are recorded for each test culture.

Claim 7: Modifying the test kits of MDS to be cytapheresis pouches would have been obvious to one of ordinary skill in the art as a choice of design.

Claim 8: FIGS. 2 and 5 illustrate the process for carrying out control tests.

Claim 10: Any task defined in FIGS 2 or 5 constitute a management task.

Claim 11: The laboratory information system of MDS is connected to a network of laboratory computers (FIG. 1).

Claim 12: A dialysis procedure is a form of cell therapy.

Claim 13: Using the cell testing system of MDS in association with gene therapy as opposed to dialysis would have been obvious to one of ordinary skill in the art as a choice of design.

Claim 14: Any usage of a system constitutes training on that system.

Remarks

Applicant's amendments have generated a new grounds of rejection under 35 USC 112, as explained in this action.

Applicant's arguments regarding the MDS reference have been considered.

(1) Applicant argues that MDS does not disclose a method for processing information that involves a operational entity and a preparation laboratory. However, as described in the

Art Unit: 2166


above action, MDS discloses an operational entity (22, 26, 27, 30) and a preparation laboratory having workstations (10).

(2) Applicant argues that after each functional stage, MDS does not disclose sequential and conditional validation of each stage. However, as stated in the final office action of 12/2/02, MDS discloses such a feature in FIGS. 2 and 5, which contain decision points (illustrated by diamond shaped blocks) that read as sequential and conditional validation steps.

(3) Applicant argues that MDS does not disclose the inputting of post-reinjection follow-up information. However, page 6, line 17 contains a discussion of subsequent tests that may be performed on biological samples that can be entered in to the computer system of MDS. Since subsequent tests can be performed at any time after an original set of tests, such tests could occur after a re-injection of cells, and could accordingly read as post-re-injection follow up information.

This office action is not made final.

Any inquiry concerning this communication should be directed to Sam Rimell at telephone number (703) 306-5626.


Sam Rimell
Primary Examiner
Art Unit 2166